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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/696,709

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Edward W. Merrill

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EXAMINER

BERMAN, SUSAN W

ART UNIT

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1796

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/696,709	Applicant(s) MERRILL ET AL.	
	Examiner /Susan W. Berman/	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-134 is/are pending in the application.
- 4a) Of the above claim(s) 128-134 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124-127 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2-21-08</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment & Arguments

Applicant's arguments filed 02/21/2008 have been fully considered but they are not persuasive.

With respect to the rejections under 35 USC 112, first paragraph, applicant submits that the claims are fully supported by the specification. This argument is not persuasive. It is noted again that the instant claim language is also not supported by the disclosures of 08/600,744 or 08/726,313 and thus not entitled to the earlier priority dates thereof for reasons of record.

Applicant has pointed to disclosure for polyethylene heated at or above its melting temperature for about 5 minutes to about 3 hours and for heating to about 175⁰C (melting point according to Declaration evidence) and cooling the heated and irradiated polyethylene. Absent a specific definition in the instant specification, “pre-heating” is understood to mean heating with a concurrent change in temperature before a subsequent process step and “pre-annealing” is understood to mean maintaining an article at a specific temperature for a specified time period followed by gradual cooling at a predetermined rate before a subsequent process step. See Hawley’s “Condensed Chemical Dictionary, tenth Edition, pages 74 and 518. This definition of “pre-annealing” is also consistent with the disclosure of Saum et al, column 6, lines 34-46, referred to by applicant. The instant specification, as filed, does not mention “pre-annealing” or the temperatures, times or cooling rate for “pre-annealing” in the disclosed processes. What is disclosed is “pre-heating to a temperature below the melting temperature of the UHMWPE” in the WIR-SM or WIR-AM method disclosed. The disclosed MIR method teaches melting the UHMWPE, which is not considered to be equivalent to “pre-annealing”, as set forth in the instant claims, or to “pre-heating”, as disclosed in the WIR methods in the instant specification.

Applicant points to Example 3, page 41, to support recitation of “pre-annealing”. However, the process in Example 3 does not disclose a “pre-annealing” step before irradiation. What is disclosed is “pre-heating” followed by irradiation and then followed by cooling to room temperature. Furthermore, the term “pre-annealing” is not employed to describe the disclosed process.

With respect to the recitation “period of time greater than 30 minutes”, the disclosure on page 30 of a time period of about 30 minutes to about 2 hours is a description of the time period for maintaining the UHMWPE above the melting temperature before irradiation in the MIR embodiment. The description of cooling slowly in the MIR process is a process step following irradiation and not a disclosure of “pre-annealing”, as argued by applicant.

While applicant may argue that heating prior to irradiation followed by cooling after irradiation may be broadly considered “annealing”, the process described is not considered to meet the requirements for a “pre-annealing” step in the instantly claimed process. Applicant’s claim language recites pre-annealing, irradiating to crosslink and quenching of residual free radicals. While there is no recited order of steps with respect to “pre-annealing”, irradiation and quenching, the use of the term “pre-annealing” is interpreted to set forth annealing before irradiating and quenching free radicals. If applicant intends to simultaneously anneal and irradiate the UHMWPE, it should be so stated. No cooling step as a predetermined rate is recited so it is not clear when the “pre-annealing” starts or stops. The cooling step recited in claim 125 is not defined as part of the “pre-annealing” step recited in claim 124. Claims 126 and 127 recite that the quenching of free radicals is subsequent to irradiation but does not clarify when the “pre-annealing” step takes place.

Shalaby et al: It is agreed that Shalaby et al teach melting UHMWPE powder in contact with UHMWPE fibers to obtain a reinforced composite by heating for a time necessary to melt the powder and then cooling the composite. Shalaby et al disclose heating sheets of polymeric matrix and reinforcement to a temperature and for a time to melt the film and coat the reinforcement so that a unitary solid is produced upon cooling. The composite is then treated with high energy radiation in the presence of acetylene in order to sterilize and crosslink the composite UHMWPE. Radiation causes free radicals to form that are then “quenched” by crosslinking in the presence of acetylene. Thus the steps set forth in the instant claims are disclosed.

Applicant argues that neither Shalaby et al nor Sun et al discloses quenching free radicals formed upon irradiation. This argument is not persuasive for the following reasons. It is noted that the claim recitation “and quenching residual free radicals...preform” does not limit the manner of quenching free radicals. Shalaby et al clearly teach that high energy radiation crosslinks the UHMWPE in column 6, lines 1-7. Furthermore, Shalaby et al teach that the composite can be irradiated in the presence of acetylene which would be expected to enhance crosslinking (recombination of free radicals). Shalaby et al teach that the crosslinked UHMWPE composites may be irradiation sterilized without decline in physical properties, thus teaching that free radicals have been quenched in the disclosed process (column 2, lines 45-58). Sun et al specifically teach quenching free radicals remaining after irradiation by heat treatment followed by cooling (column 6, lines 48-51, and column 8, lines 11-20).

The double patenting rejections of record are maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 124-127 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner has not found any disclosure of “pre-annealing” or pre-annealing “at a temperature greater than ambient temperature and less than the decomposition temperature” or for a “period of time greater than about 30 minutes” of UHMWPE. The examiner has not found any disclosure of “quenching residual free radicals” in the UHMWPE preform. With respect to claim 125, the examiner has not found any disclosure of cooling after the “quenching step” to a “temperature below the melting temperature” of the polyethylene. Applicant is reminded that claim language should correspond to the description as filed. Applicant discloses “pre-heating to a temperature below the melting temperature of the UHMWPE” in the WIR-AM method disclosed.

US 5,879,400 discloses a method wherein polyethylene is “heated at or above its melting temperature” for a “period of about 5 minutes to about 3 hours”, then irradiated to crosslink, then cooled at a rate equal to or greater than about 0.5⁰ C/min., and is then machined or compression molded (column 2, lines 30-52). The examples disclose heating to about 175⁰C and holding at

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the steady state temperature for 30 minutes before starting irradiation, followed by irradiating and cooling at a rate of about 0.5⁰ C/min. and then by machining.

US SN 08/726,313, filed 10-02-1996, includes the disclosure of melt irradiation set forth in US '400 and also discloses variations on irradiation (warm or cold) followed by melting so that there are substantially no detectable free radicals. The method of WIR-SM includes pre-heating UHMWPE to a temperature below the melting point, irradiating and subsequent melting. This disclosed method appears to be closest to the instantly claimed method but fails to provide support for the wording used in the instant claims. There is no mention of pre-annealing, decomposition temperature, quenching, or a time period greater than about 30 minutes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 124-127 are rejected under 35 U.S.C. 102(e) as being anticipated by Shalaby et al (5,824,411). Shalaby et al disclose a method that comprises melting an UHMWPE “construct polymer-fiber” and irradiating the resulting composite with high energy radiation to sterilize and crosslink composites of the UHMWPE. See column 2, lines 11-27, column 3, lines 9-18, column 5, line 32, to column 6, line 10, and Examples 1 and 5. Shalaby et al disclose heating sheets of

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polymeric matrix and reinforcement to a temperature and for a time to melt the film and coat the reinforcement so that a unitary solid is produced upon cooling. The composite is then treated with high energy radiation in the presence of acetylene in order to sterilize and crosslink the composite UHMWPE. Radiation causes free radicals to form that are then “quenched” by crosslinking in the presence of acetylene.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 124-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al (5,414,049). Sun et al teach a method for forming a medical implant comprising annealing a medical implant and then radiation sterilizing the implant. The irradiated implant is then further annealed to reduce free radicals. The difference from the instantly claimed process is that Sun et al teach treating a formed implant rather than a preform. It would have been obvious to one skilled in the art at the time of the invention to apply the process steps taught by Sun et al to a polyethylene preform. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of imparting the desirable properties taught by Sun et al to a preform material since the polymeric material is polyethylene in the implant and in the preform.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-133 of copending Application No. 10/948440. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. irradiating and heating a polyethylene article, are set forth in the claims of '440 and in the instant claims. The instantly claimed step of heating to a temperature less than the decomposition temperature is considered to encompass the melting step set forth in the claims of '440. Alternatively, the melting step set forth in the claims of '440 corresponds to the step of quenching free radicals set forth in the instant claims and the comprising language of the claims of '440 encompasses the pre-annealing step in the instant claims. With respect to claims 126 and 127, It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '440.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124, 126-129 and 135-137 of copending Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of '209 and in the instant claims. With respect to claims 126-127, It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '209.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129 of copending Application No. 10/696362. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the UHMWPE are set forth in the claims of '362 and in the instant claims. The step of heating above the melting temperature set forth in the claims of '362 is encompassed by the step of pre-annealing at a temperature less than the decomposition temperature of polyethylene set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 114 and 124-129 of copending Application No. 10/901089. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the heated UHMWPE are set forth in the claims of '089 and in the instant claims. The step of heating above the melting temperature set forth in the claims of '089 is encompassed by the step of pre-annealing at a temperature less than the decomposition temperature of polyethylene set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
4/24/2008

/Susan W Berman/
Primary Examiner
Art Unit 1796

Application Number 	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/696,709	MERRILL ET AL.	
	Examiner	Art Unit	
	/Susan W. Berman/	1796	